(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 January 2005 (27.01.2005)

PCT

(10) International Publication Number
WO 2005/006955 A2

(51) International Patent Classification[7]: A61B

(21) International Application Number:
PCT/US2004/022137

(22) International Filing Date: 9 July 2004 (09.07.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/618,140 10 July 2003 (10.07.2003) US

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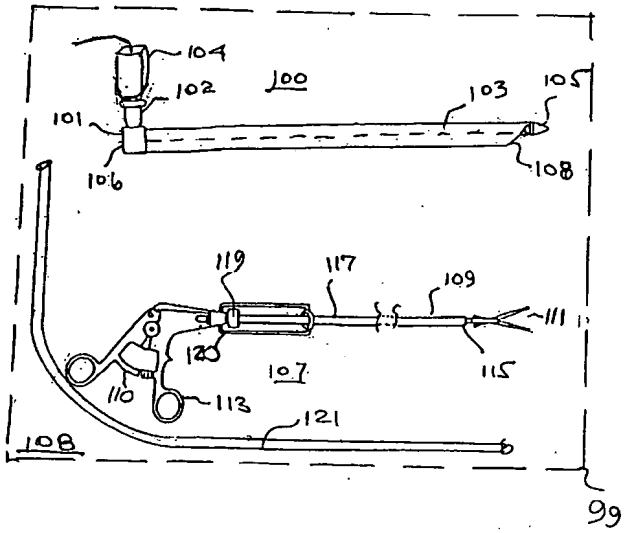
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

[Continued on next page]

(54) Title: ENDOSCOPIC EPICARDIAL ABLATION ABOUT PULMONARY VEINS



(57) Abstract: Surgical instruments and procedures promote placement of a tissue ablating probe surrounding the left and right pulmonary veins within the intrapericardial space of a patient's heart via access through a subxiphoid or subcostal entry incision. An opening is formed in the pericardium near the apex region of the heart to facilitate formation of openings through three pericardial reflections by which a tissue-ablating probe is positioned around the pulmonary veins. A kit of the surgical instrument required to perform the tissue-ablating surgical procedure is assembled within an hermetically-sealed enclosure.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ENDOSCOPIC EPICARDIAL ABLATION ABOUT PULMONARY VEINS

Field of the Invention:

[0001] This invention relates to methods and apparatus for ablating tissue about the pulmonary veins with diminished risk of collateral injury during placement of an ablation probe or sheath therefore.

Background of the Invention:

[0002] One clinically recognized treatment for chronic atrial fibrillation includes ablating the tissue surrounding the pulmonary vein ostia at the site in the intrapericardial space where the veins enter into the atria. Cardiac surgeons have described entering the chest through multiple thoracotomy incisions, using an endoscope and endoscopic instruments to dissect a tract under the superior vena cava and the inferior vena cava, and threading an ablation probe around the four pulmonary veins. In some of these cases, a surgical robot has been used to assist in the procedure. The probe enters posterior to the superior vena cava, winds through the transverse sinus of the pericardium, loops around the four pulmonary veins, and exits the tract that was dissected posterior to the inferior vena cava. The tract formed posterior to the superior vena cava enters into the transverse sinus of the pericardium. The tract formed posterior to the inferior vena cava completes the path of the ablation probe around the pulmonary veins.

[0003] In another technique to perform robotic probe placement endoscopically, one endoscope is advanced through a thoracotomy incision, or other entry incision, into the intrapericardial space adjacent the superior vena cava, and an endoscopic tool is inserted into the right pleural cavity via another thoracotomy incision. This latter endoscopic tool in the right pleural cavity is used to dissect through the right medial pleura and the pericardium posterior to the superior vena cava while being viewed with the endoscope. It is desirable to

perform an ablation procedure using one set of endoscopic equipment and one endoscopic cannula.

[0004] In addition, encirclement of all four pulmonary veins with an epicardial ablation probe is hampered by two folds (known as reflections) of pericardium. One pericardial reflection forms the end of the transverse pericardial sinus and extends between the superior vena cava and the right superior pulmonary vein. The other pericardial reflection extends between the inferior vena cava and the right inferior pulmonary vein. It is relatively easy to dissect through the latter pericardial reflection, using an endoscopic subxiphoid cannula and a pericardial entry instrument. With the endoscopic subxiphoid cannula placed behind the heart in the oblique pericardial sinus, the pericardial reflection between the inferior vena cava and the right inferior pulmonary vein may be grasped by a pericardial entry instrument under endoscopic visualization, and an opening created through the reflection.

[0005] With the pericardial reflection between the superior vena cava and the right superior pulmonary vein, access is more difficult because this reflection forms the end of the transverse pericardial sinus and there is no direct way for the endoscopic subxiphoid cannula to approach this pericardial reflection. Without direct access and good visualization of this pericardial reflection, dissection is hazardous because the superior vena cava, right superior pulmonary vein, and right main pulmonary artery are all in the vicinity of the reflection. Grasping and forming a hole in the wrong structure, for example, the superior vena cava, would be disastrous.

Summary of the Invention:

[0006] In accordance with one embodiment of the present invention a procedure for traversing the pericardial reflection between the superior vena cava and the right superior pulmonary vein includes positioning an endoscopic subxiphoid cannula to place an ablation probe or a sheath into the transverse

pericardial sinus and advance the ablation probe or sheath to the end of the transverse sinus. The endoscopic subxiphoid cannula is removed from the body, leaving the ablation probe or sheath in place, and is then reinserted and advanced to the oblique pericardial sinus. A pericardial entry instrument is inserted into the working channel of the subxiphoid cannula and used to grasp the pericardial reflection that forms the floor or base of the transverse pericardial sinus. When the floor of the transverse pericardial sinus is entered, the ablation probe or sheath should be visible. The ablation probe or sheath is pulled partially out of the transverse pericardial sinus, allowing the endoscopic subxiphoid cannula to visualize the pericardial reflection at the end of the transverse sinus. The pericardial entry instrument is used to grasp and form an opening through this reflection, and the grasper of the pericardial entry instrument grasps the ablation probe or sheath and advances it through the opening and laterally to the right superior and inferior pulmonary veins. The endoscopic subxiphoid cannula is then positioned in the oblique pericardial sinus, and the pericardial entry instrument is used to create an opening in the pericardial reflection between the inferior vena cava and the right inferior pulmonary veins. The ablation probe or sheath, now lying lateral to the right superior and inferior pulmonary veins, is grasped by the graspers of the entry instrument and pulled into the oblique pericardial sinus to complete the encirclement of all four pulmonary veins.

[0007] In accordance with another embodiment of the present invention, an endoscopic subxiphoid cannula is inserted via a left subcostal incision instead of a subxiphoid incision. The apex of the human heart lies in the left chest rather than at the midline. An incision approximately 1 cm below the left costal margin, at approximately the midclavicular line, may enable a closer, more direct access to the apex of the heart with the endoscopic subxiphoid cannula. With this technique, a 1.5 - 2.0 cm incision is made 1 cm below the costal margin. The anterior rectus sheath is incised, the rectus muscle is spread bluntly to expose the posterior rectus sheath, and a 1.5 – 2.0 cm incision is performed in the

posterior rectus sheath. A gloved finger is inserted in the incision and advanced to the inferior border of the costal margin. The endoscopic subxiphoid cannula is inserted in the subcostal incision and advanced through the muscular fibers of the diaphragm into the left pleural cavity. The apex of the heart is identified, and the pericardial entry instrument is used to grasp the pleura overlying the apex and create an opening in the pleura to expose the pericardium. The pericardium is grasped with the pericardial entry instrument and is cut to form an access opening through the pericardium. The tapered conical tip of the endoscopic subxiphoid cannula is inserted through the pericardial opening to access the heart during the procedure previously described.

Brief Description of the Drawings:

[0008] Figure 1 is an anatomical view of the pericardial sac with the heart removed to illustrate the sinuses and reflections about the pulmonary veins;

[0009] Figures 2 a, b, c comprise a flow chart of a surgical procedure performed in accordance with the present invention via a subxiphoid entry;

[0010] Figures 3 a, b comprise a flow chart of a surgical procedure performed in accordance with the present invention via a subcostal entry; and

[0011] Figure 4 is a perspective view of a kit of surgical instruments for performing a surgical procedure according to the present invention.

Detailed Description of the Invention:

[0012] Referring now to the simplified anatomical illustration of Figure 1, there is shown a view of the pericardial sac (with the heart absent), as viewed frontally. In this view, there is shown the reflection 9 disposed between the inferior vena cava and the right inferior pulmonary vein. Additionally, this view shows the reflection 11 disposed between the superior vena cava and the right superior pulmonary vein. Also, this view shows the reflection 13 that forms the base of the transverse pericardial sinus 15. The objective of the surgical

procedure performed in accordance with an embodiment of the present invention is to encircle the right and left pulmonary veins with a tissue-ablation probe (or sheath through which the ablation probe may be positioned) in order to ablate atrial tissue along a path substantially encircling the ostia of these veins. This is accomplished with diminished risk of penetration of the veins and arteries in the vicinity and with minimal damage or trauma to adjacent tissue. As used herein, a reflection' is a fold of tissue, in this case, the pericardium, that may form a barrier between sinuses or regions within the intrapericardal space.

[0013] Referring now to the flow chart of Figure 2, there is shown one procedure for surrounding the pulmonary veins with an ablation probe or sheath. Specifically, the surgical procedure includes forming 17 a subxiphoid skin incision and bluntly dissecting 19 through the incision to expose the linea alba. The linea alba is then excised 21 and a finger is inserted to dissect tissue and thereby form a tract 23 to underside of the xiphoid process and sternum.

[0014] An endoscopic cannula 24, for example as illustrated in Figure 4, includes a tapered transparent tip 26, and is inserted 25 through the subxiphoid incision 17 and advanced 27 through the diaphragm to the anterior surface of the pericardium. Fat tissue on the anterior surface of the pericardium is bluntly dissected 29 in preparation for entry into the pericardium.

[0015] An instrument for forming an entry opening in the pericardium is inserted 31 through a working channel in the endoscopic cannula to grasp 33 a bleb or form a tent of the pericardium near the apex of the heart. An overlying tubular cutter is advanced over the grasped pericardium to cut an opening therethrough for accessing the intrapericardial region.

[0016] The endoscopic cannula may now be advanced 35 through the opening cut in the pericardium for inserting 37 through the instrument channel therein an ablation probe or sheath that is then advanced into the transverse pericardial sinus. The ablation probe or sheath therefor is left in place within the transverse pericardial sinus as the endoscopic cannula is removed 41 from the

body. The endoscopic cannula may now be reinserted 43 through the subxiphoid incision along side the ablation probe (or sheath) and into the oblique pericardial sinus. An entry instrument is inserted through the working channel of the endoscopic cannula toward the reflection 13 that extends substantially between the right and left superior pulmonary veins, and that therefore forms the base of the transverse pericardial sinus. A bleb or tent of this reflection 13 is grasped 45 and an overlying tubular cutter is rotated through the grasped reflection to form an opening 47 into the transverse pericardial sinus. The ablation probe (or sheath) that was positioned in the transverse pericardial sinus during the procedural step 39 may now be retracted 49 partially from the transverse pericardial sinus.

[0017] Next, a bleb or tent of the reflection 11 at the end of the transverse pericardial sinus disposed between the superior vena cava and the right superior pulmonary vein is grasped 51 using the instrument for forming an entry opening in the pericardium that is inserted through a working channel in the endoscopic cannula, and an overlying tubular cutter is rotated to form an opening 53 through the grasped reflections.

[0018] Now, the tissue-grasping end effector of the entry instrument may be manipulated through the opening formed in the reflection 13 to grasp the ablation probe (or sheath) to manipulate its advance 55 through the opening formed in the reflection 11. With the probe (or sheath) disposed in the transverse pericardial sinus and through the reflection 13 at the end thereof, the endoscopic cannula, with the entry instrument disposed within the instrument channel, may then be repositioned within the oblique pericardial sinus 57 in order to grasp 59 a bleb or tent of the reflection 9 between the inferior vena cava and the right inferior pulmonary vein using the grasping end effector of the entry instrument. An overlying tubular cutter then cuts the grasped reflection to create an opening 61 in the reflection 9. The endoscopic cannula with the entry instrument disposed in the instrument channel may now be positioned 63 through the opening formed in

the reflection 9, and the grasping end effector of the entry instrument is used to grasp the ablation probe (or sheath) extending through the reflection 13. The grasped ablation probe (or sheath) is then pulled through the opening in the reflection 9 into the oblique pericardial sinus 65 where the retrieved end and mid-length of the ablation probe may be linked and grasped to form a loop 67 around the four pulmonary veins. The ablation probe of conventional design thus positioned (or advanced 68 through the sheath to such position) may now be energized 69 to ablate atrial tissue in the looped path surrounding the pulmonary veins.

[0019] Referring now to the flow chart of Figure 3, there is shown another method embodiment of the present invention for accessing the heart of a patient in which an initial subcostal entry incision is formed 71. Tissue is then bluntly dissected 73 to expose the anterior rectus sheath, and an incision is formed 75 therein. The rectus muscle is spread 77 to expose the posterior rectus sheath, and an incision 79 is formed therein. Finger dissection of tissue exposed through the incision in the posterior rectus sheath then forms a tract 81 to the inferior border of the costal margin. An endoscopic cannula having an instrument channel therein is inserted 83 into the dissected tissue tract and is advanced through the muscular diaphragm 85 into the pleural cavity. A pericardial entry instrument is inserted into the instrument channel of the endoscopic cannula 87 and is advanced therein toward the apex region of the heart. A bleb or tent of the pleura overlying the heart near the apex region is grasped via the entry instrument 89, and an overlying tubular cutter is advanced through the grasped pleura to form an opening therein 90. The entry instrument may then be advanced through the opening formed in the pleura to grasp a bleb or tent of the pericardium 91 near the apex region of the heart. The overlying tubular cutter is advanced through the grasped pericardium to form an opening 93 in the pericardium. The endoscopic cannula may then be advanced through the opening thus formed in the pericardium 95 to access the regions of the heart, for

example, to prepare atrial tissue surrounding the ostia of the four pulmonary veins for ablation substantially in the manner as previously described herein.

[0020] Referring now to Figure 4, there is shown a kit of the surgical instruments assembled for use in positioning an ablation probe (or sheath therefor) about the four pulmonary veins, for example, in the manner as previously described herein. Specifically, the kit 99 includes an endoscopic cannula 100 having an elongated body 103 including an endoscopic lumen 101 and an instrument channel 106 that is disposed eccentric the endoscopic lumen 101 between proximal and distal ends of the body 103. The endoscopic cannula 100 includes a tissue-dissecting transparent tip 105 at the distal end, and an endoscope slidably received in the lumen 101 may include a video camera 102 attached in conventional manner to the eyepiece 104 of the endoscope at the proximal end thereof. The eyepiece and video camera are disposed at right angle relative to the instrument channel 106 to avoid interfering with surgical instruments inserted in the instrument channel 106. The distal end 108 of the instrument channel 106 is chamfered or skewed at an oblique angle relative to the elongated body to facilitate easy entry through pericardial and pleural openings. The proximal end of the instrument channel 106 is displaced from the distal end thereof by a sufficient distance to remain outside of a patient's body during a surgical procedure, for example, as previously described herein in which the distal end of endoscopic cannula is disposed within the intrapericardial region of a patient's heart along a tract through a subxiphoid or subcostal entry incision.

[0021] The kit 99 also includes a pericardial entry instrument 107 that includes an elongated body 109 which supports a pair of jaws 111 that are coupled through the body 107 to scissor-like handles 113 mounted at the proximal end of the body 109 for manually controlling the grasping of tissue by the jaws 111. A ratcheting locking mechanism 110 retains the jaws 111 in locked position. The body 109 also supports thereon an overlying tubular cutter 117 having a sharpened distal end 115 and a thumb wheel 119 disposed near the

proximal end for manually advancing and rotating the cutting edge through tissue grasped by the jaws 111. Stop mechanism 120 limits the distal extent of translational movement of the tubular cutter 117. The overlying tubular cutter 117 is dimensioned to slide and rotate within the instrument channel 106 of the endoscopic cannula 100. The elongated body 109 has sufficient length to extend through the instrument channel 106 and distally thereof into the visual field of an endoscope disposed within the endoscopic lumen 101. Of course, an endoscope with eyepiece 102 and video camera 104 need not be packaged within the kit 99 but may instead be separately provided in sterile condition for assembly within the endoscopic cannula 100. The kit 99 of instruments may also contain the hollow ablation sheath 121 which may include a guide wire therein. Such guide wire facilitates placement of the sheath around the pulmonary veins with the aid of the instrument channel 106 and grasping jaws 111 of the entry instrument 107, substantially in accordance with the surgical procedure as previously described herein. After placement of the sheath 121 surrounding the pulmonary veins, any guide wire therein may be removed and replaced with a tissue-ablating probe of conventional design that slides within the sheath to substantially surround the pulmonary veins. In operation, with the sheath and ablation probe therein positioned about the pulmonary veins, the ablation probe may be energized in conventional manner to ablate atrial tissue, for example, in a surgical procedure substantially as previously described herein.

[0022] The endoscopic cannula 100 and entry instrument 107 and, optionally, the sheath 121 for an ablation probe are packaged in the enclosure 108 that is formed, for example, as an hermetically-sealed carton or envelope to confine the instruments within a sterile environment.

[0023] Therefore, the method and surgical instrument in accordance with the present invention greatly facilitate the positioning of a tissue-ablating probe about the pulmonary veins via a subxiphoid or subcostal entry incision, with

diminished risk of puncturing the superior vena cava or causing other unintended trauma during a surgical procedure.

What is claimed is:

1. A kit of surgical instruments for ablating tissue in the heart of a patient, the kit comprising:

a cannula including an elongated body having one lumen therein for supporting an endoscope therein, and including a transparent tip disposed at a distal end of the body substantially aligned with an endoscope therein, the elongated body including another lumen disposed offset from the one lumen for slidably supporting a surgical instrument therein;

a first surgical instrument including an instrument body having a tissue-grasping end effector that is mounted at a distal end thereof and that is linked through the instrument body to a manual actuator disposed at a proximal end of the instrument body for remotely manipulating the end effector from the proximal end, the first surgical instrument including a tubular element slidably and rotably overlying the instrument body and having a tissue-cutting distal end thereon for cutting tissue grasped by the end effector, the tubular element being configured and dimensioned to slide and rotate within said another lumen of the endoscopic cannula; and

an enclosure surrounding the endoscopic cannula and the first surgical instrument in a substantially sterile environment.

2. The kit according to claim 1 including a second instrument having a hollow sheath with a bore therethrough for receiving a tissue-ablating probe therein, the sheath having a sectional dimension sized to slide within said another lumen of the endoscopic cannula and being disposed in the environment within the enclosure.

3. The kit according to claim 1 including an endoscope disposed within the endoscopic cannula with a distal viewing end of the endoscope aligned with the transparent tissue-dissecting top and with a proximal end of the endoscope disposed adjacent a proximal end of the endoscopic cannula.

4. The kit according to claim 3 in which the endoscope includes near the proximal end thereof a viewing port that is skewed relative to said another lumen to avoid obstruction thereof.

5. The kit according to claim 1 in which a distal end of said another lumen includes an end face in a plane that is skewed relative to the elongated body of the endoscopic cannula to facilitate entry thereof within a tissue structure.

6. The kit according to claim 1 in which the instrument body of the first surgical instrument is dimensioned to extend within said another lumen from near a proximal end of the endoscopic cannula to beyond the transparent tissue-dissecting tip disposed at the distal end of the endoscopic cannula.

7. The kit according to claim 1 in which the endoscopic cannula is dimensioned between distal and proximal ends thereof to extend through a subxiphoid entry incision in a patient to the patient's heart.

8. The kit according to claim 1 in which the end effector of the first surgical instrument includes a pair of jaws pivotally supported at the distal end of the instrument body to operate between open and closed configurations in response to manual manipulation of the actuator disposed at the proximal end of the instrument body.

9. The kit according to claim 8 in which the actuator includes relative movable components mounted near the distal end of the instrument body for actuating the end effector to grasp tissue in response to relative movement of the components of the actuator.

10. The kit according to claim 1 in which the tubular element includes a manual actuator attached thereto near a distal end thereof, and is dimensioned to extend from the manual actuator to the tissue-cutting distal end thereof sufficiently to cut tissue grasped by the end of effector of a location distally of

the transparent tissue-dissecting tip in response to manual rotation and translation of the tubular element via the actuator attached thereto near a proximal end thereof.

11. The kit according to claim 10 includes a stop member mounted between the instrument body and tubular member for inhibiting translational movement of the tissue-cutting distal end thereof distally beyond the distal end of the end effector.

12. The kit according to claim 2 in which the sheath is flexible

13. The kit according to claim 12 in which the sheath is dimensioned to extend around the pulmonary veins of a patient from the proximal end of said another lumen of the endoscopic cannula as disposed between a subxiphoid entry incision and the heart of a patient.

14. The kit according to claim 12 in which the sheath transmits tissue-ablating energy there through at least along a distal position thereof that extends distally beyond said another lumen.

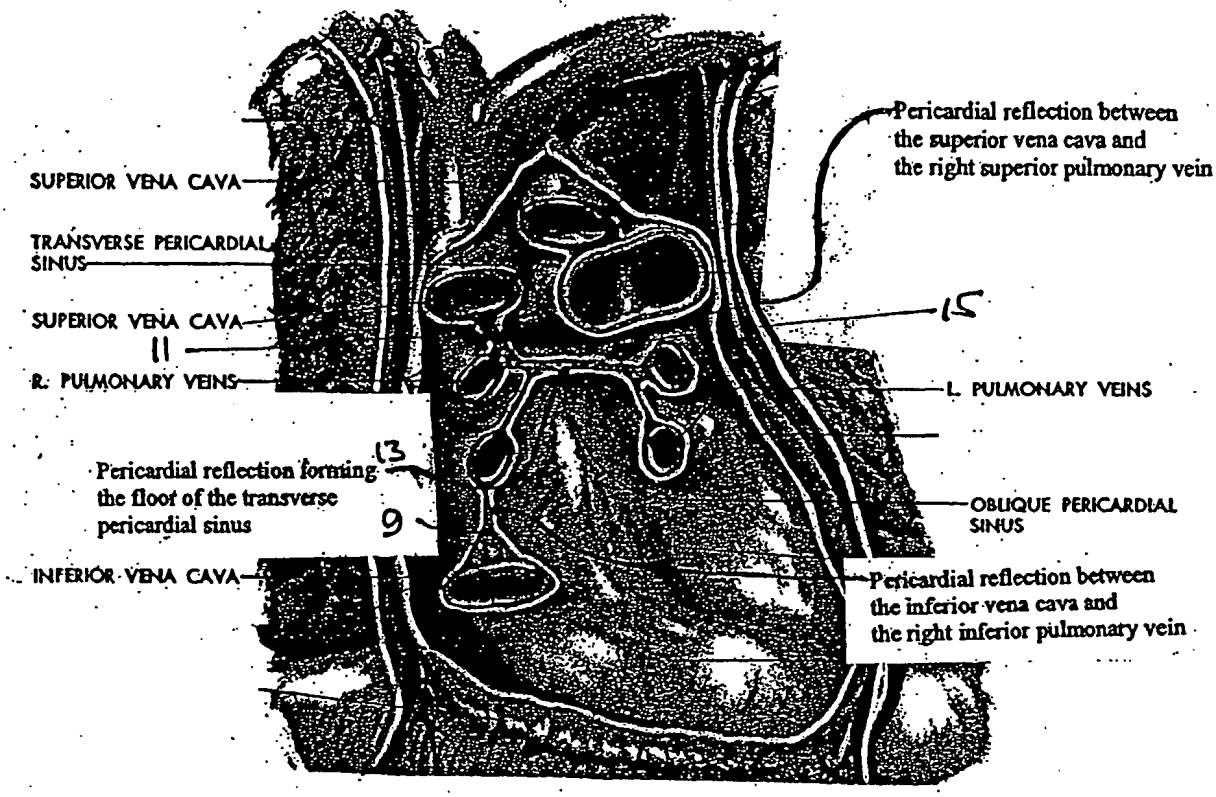

FIGURE 1

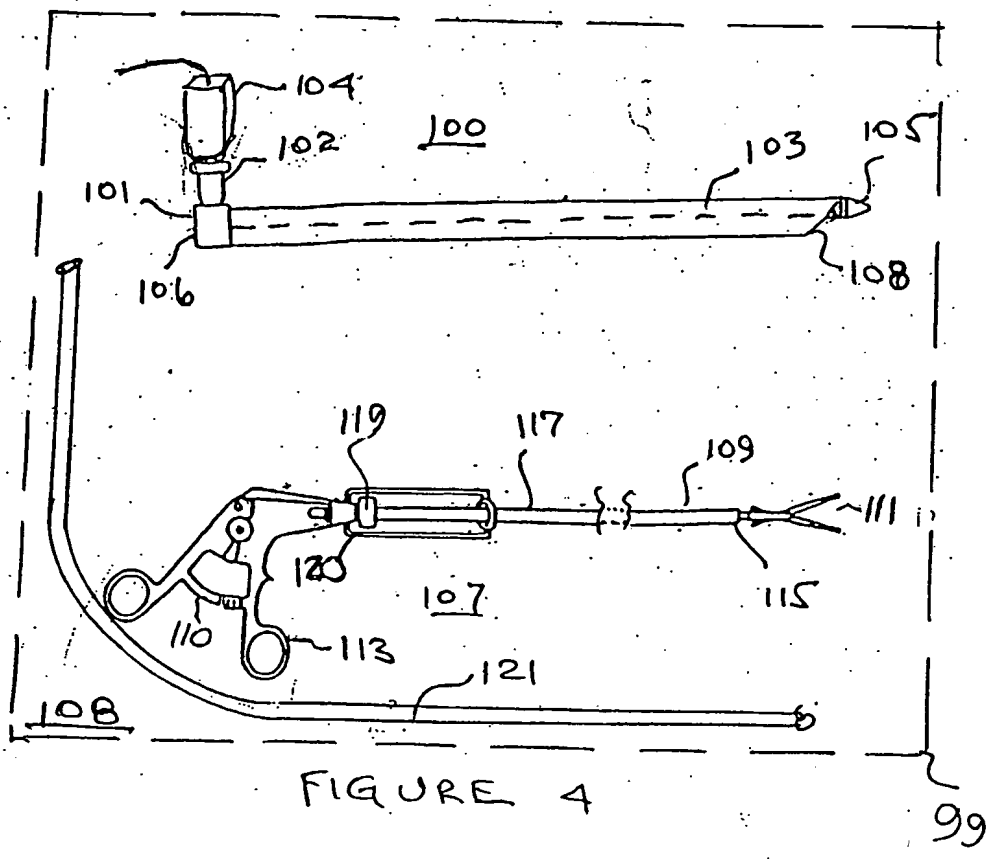

FIGURE 4

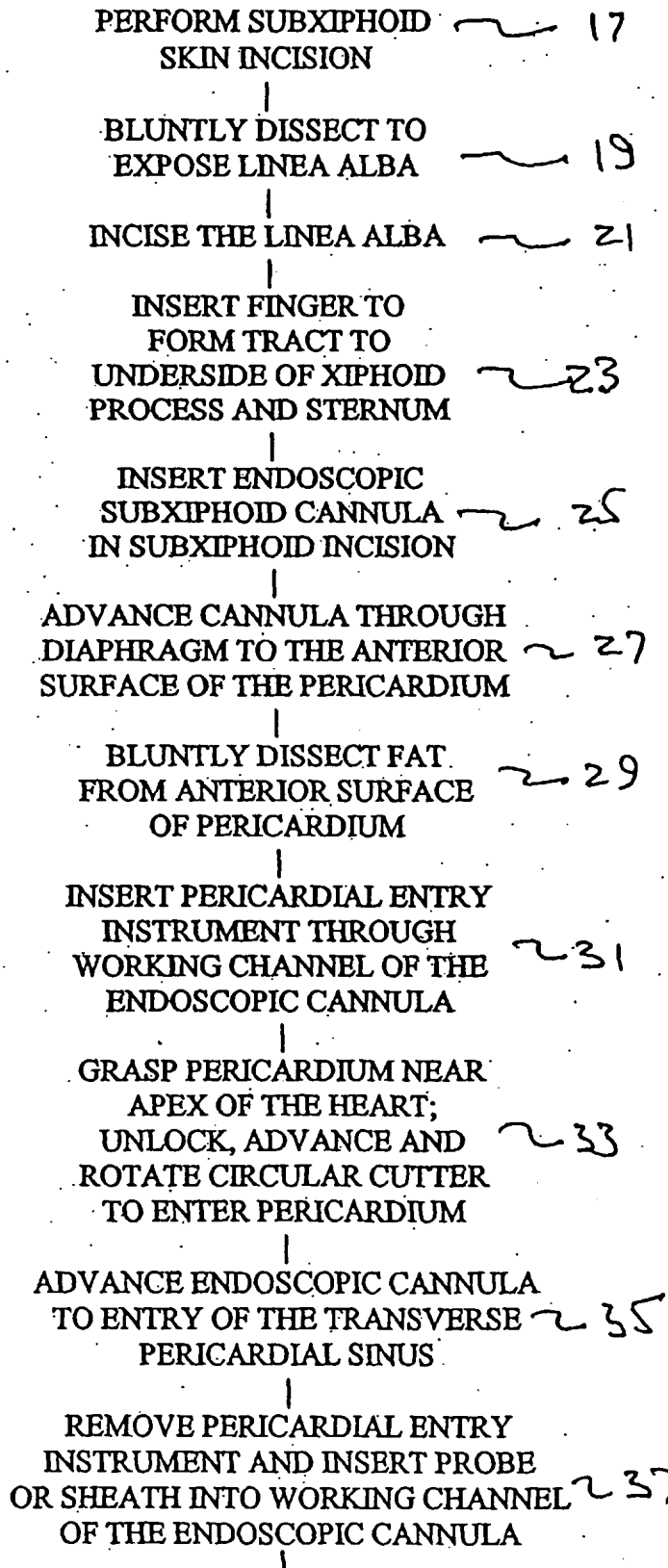
PERFORM SUBXIPHOID SKIN INCISION
17
BLUNTLY DISSECT TO EXPOSE LINEA ALBA
19
INCISE THE LINEA ALBA
21
INSERT FINGER TO FORM TRACT TO UNDERSIDE OF XIPHOID PROCESS AND STERNUM
23
INSERT ENDOSCOPIC SUBXIPHOID CANNULA IN SUBXIPHOID INCISION
25
ADVANCE CANNULA THROUGH DIAPHRAGM TO THE ANTERIOR SURFACE OF THE PERICARDIUM
27
BLUNTLY DISSECT FAT FROM ANTERIOR SURFACE OF PERICARDIUM
29
INSERT PERICARDIAL ENTRY INSTRUMENT THROUGH WORKING CHANNEL OF THE ENDOSCOPIC CANNULA
31
GRASP PERICARDIUM NEAR APEX OF THE HEART; UNLOCK, ADVANCE AND ROTATE CIRCULAR CUTTER TO ENTER PERICARDIUM
33
ADVANCE ENDOSCOPIC CANNULA TO ENTRY OF THE TRANSVERSE PERICARDIAL SINUS
35
REMOVE PERICARDIAL ENTRY INSTRUMENT AND INSERT PROBE OR SHEATH INTO WORKING CHANNEL OF THE ENDOSCOPIC CANNULA
37
TO FIG. 2b

FIGURE 2a

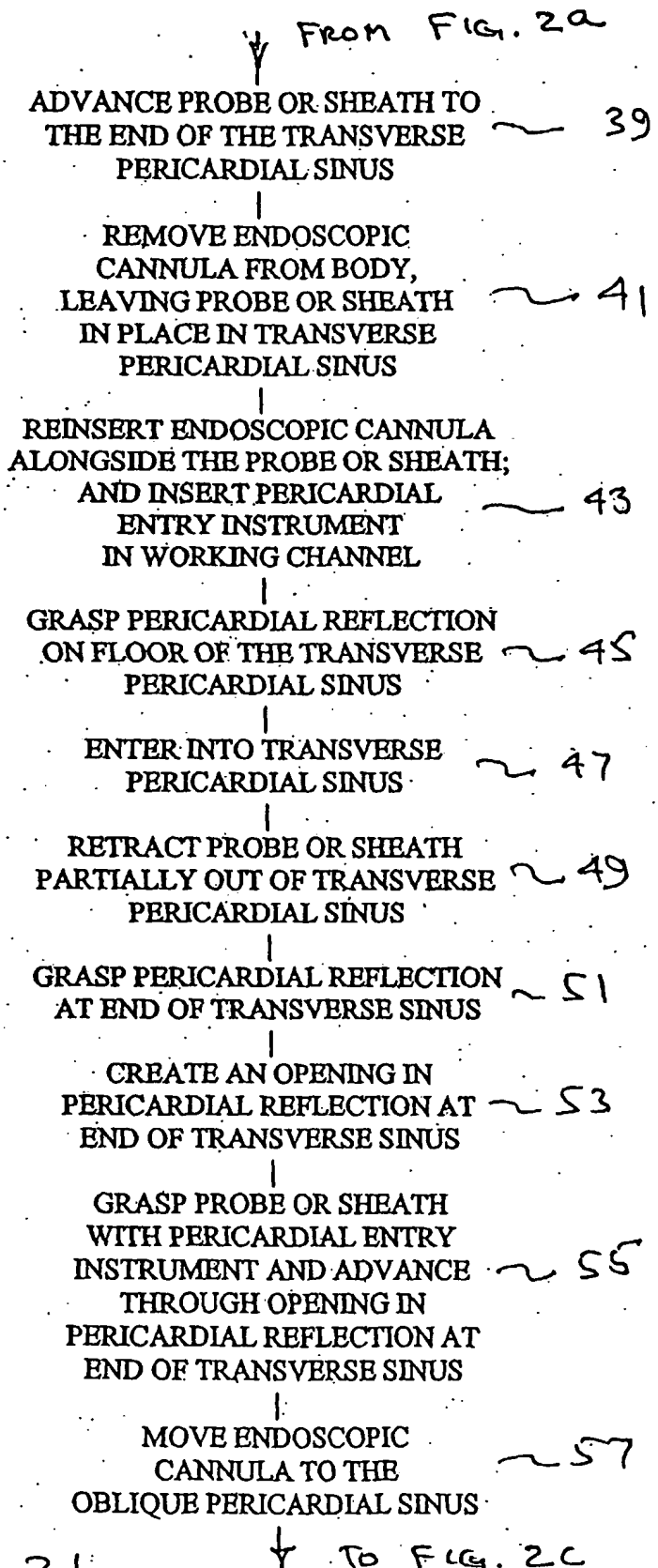
From Fig. 2a
ADVANCE PROBE OR SHEATH TO THE END OF THE TRANSVERSE PERICARDIAL SINUS
39
REMOVE ENDOSCOPIC CANNULA FROM BODY, LEAVING PROBE OR SHEATH IN PLACE IN TRANSVERSE PERICARDIAL SINUS
41
REINSERT ENDOSCOPIC CANNULA ALONGSIDE THE PROBE OR SHEATH; AND INSERT PERICARDIAL ENTRY INSTRUMENT IN WORKING CHANNEL
43
GRASP PERICARDIAL REFLECTION ON FLOOR OF THE TRANSVERSE PERICARDIAL SINUS
45
ENTER INTO TRANSVERSE PERICARDIAL SINUS
47
RETRACT PROBE OR SHEATH PARTIALLY OUT OF TRANSVERSE PERICARDIAL SINUS
49
GRASP PERICARDIAL REFLECTION AT END OF TRANSVERSE SINUS
51
CREATE AN OPENING IN PERICARDIAL REFLECTION AT END OF TRANSVERSE SINUS
53
GRASP PROBE OR SHEATH WITH PERICARDIAL ENTRY INSTRUMENT AND ADVANCE THROUGH OPENING IN PERICARDIAL REFLECTION AT END OF TRANSVERSE SINUS
55
MOVE ENDOSCOPIC CANNULA TO THE OBLIQUE PERICARDIAL SINUS
57
To Fig. 2c

FIGURE 2b

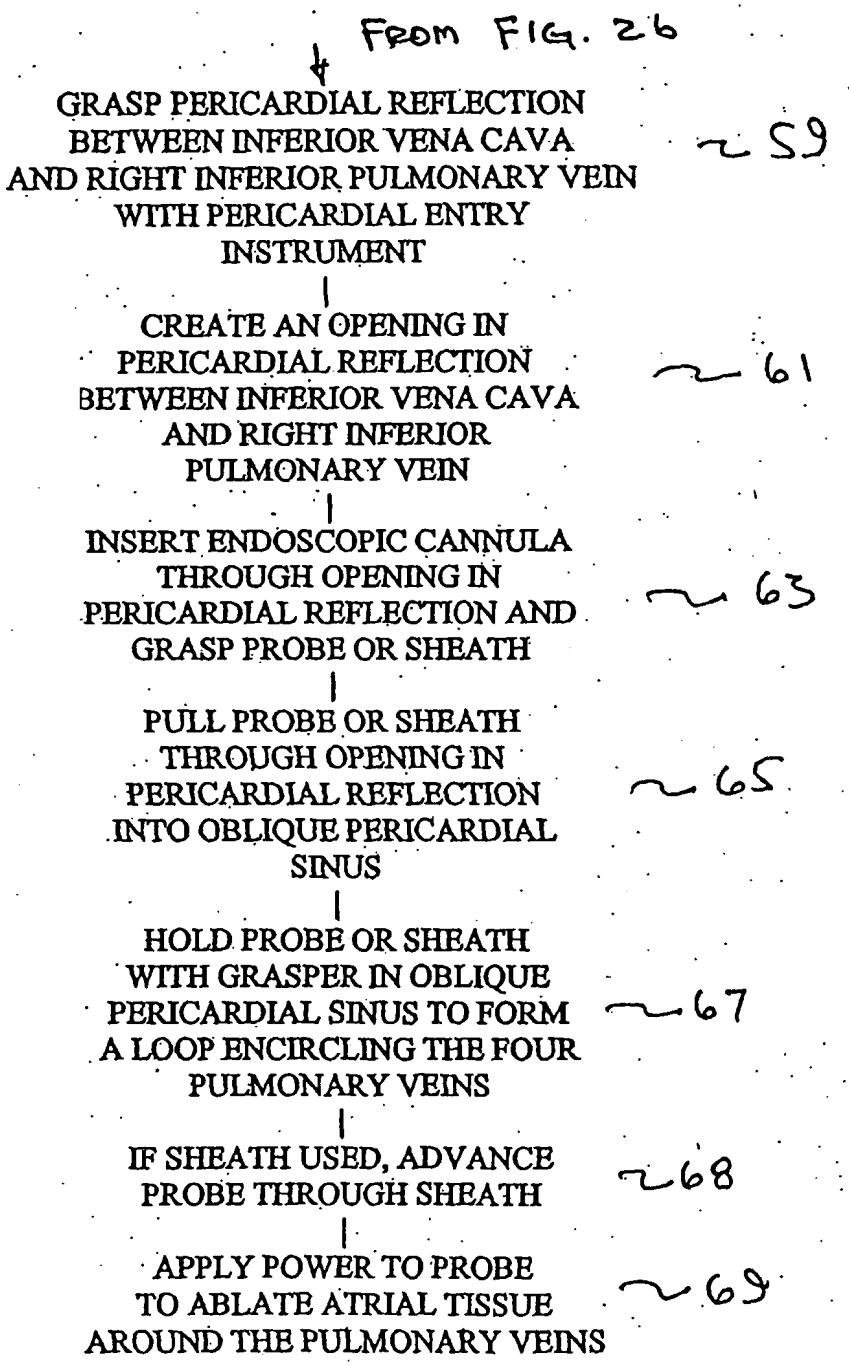
From FIG. 26
GRASP PERICARDIAL REFLECTION BETWEEN INFERIOR VENA CAVA AND RIGHT INFERIOR PULMONARY VEIN WITH PERICARDIAL ENTRY INSTRUMENT
59
CREATE AN OPENING IN PERICARDIAL REFLECTION BETWEEN INFERIOR VENA CAVA AND RIGHT INFERIOR PULMONARY VEIN
61
INSERT ENDOSCOPIC CANNULA THROUGH OPENING IN PERICARDIAL REFLECTION AND GRASP PROBE OR SHEATH
63
PULL PROBE OR SHEATH THROUGH OPENING IN PERICARDIAL REFLECTION INTO OBLIQUE PERICARDIAL SINUS
65
HOLD PROBE OR SHEATH WITH GRASPER IN OBLIQUE PERICARDIAL SINUS TO FORM A LOOP ENCIRCLING THE FOUR PULMONARY VEINS
67
IF SHEATH USED, ADVANCE PROBE THROUGH SHEATH
68
APPLY POWER TO PROBE TO ABLATE ATRIAL TISSUE AROUND THE PULMONARY VEINS
69

Figure 2C

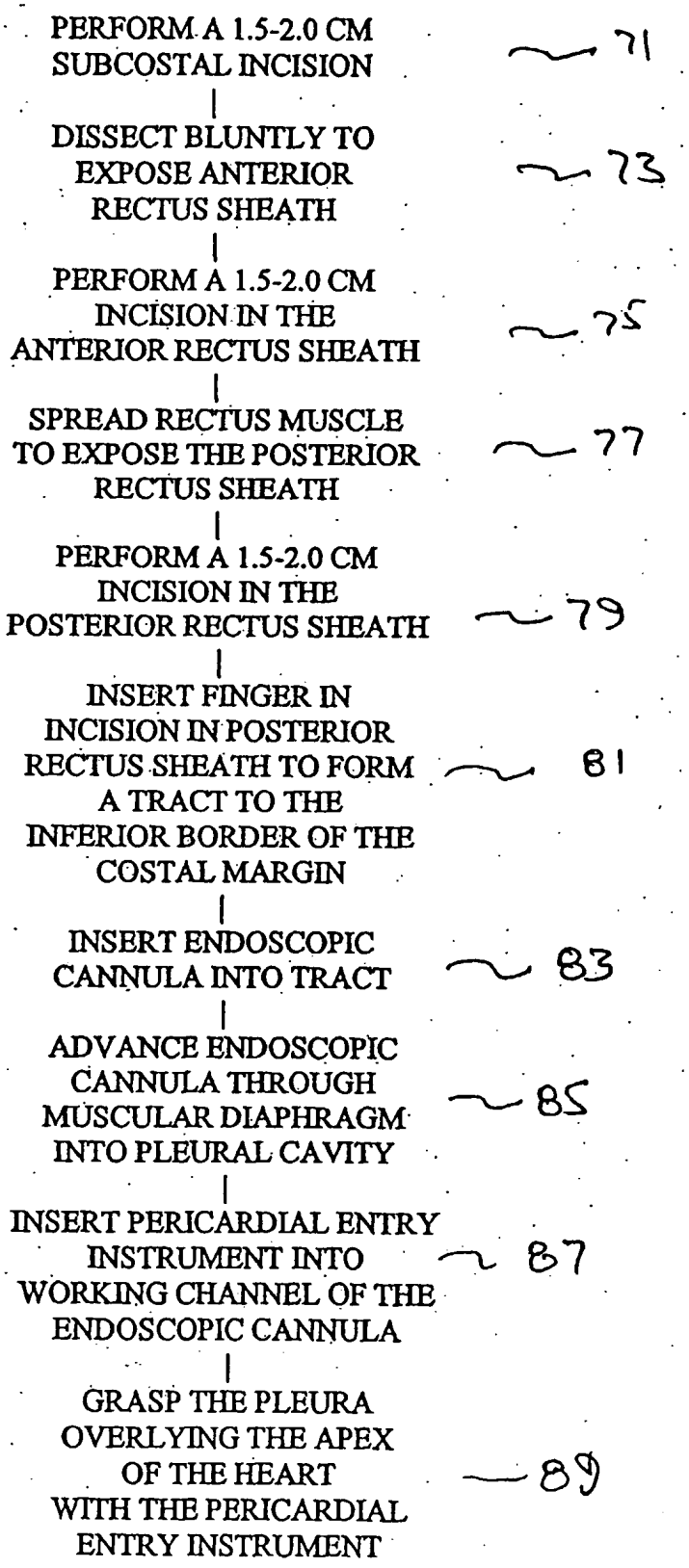

FIGURE 3a ↓ TO FIG. 3b

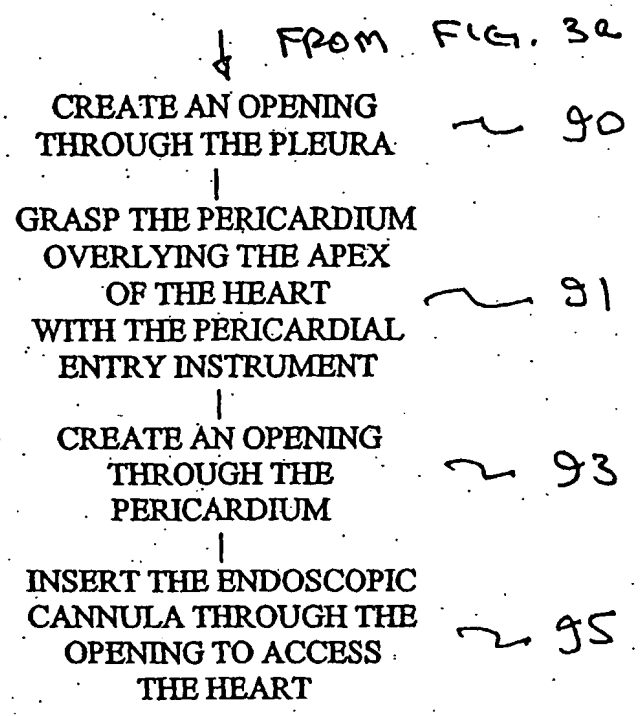
FROM FIG. 3a
CREATE AN OPENING THROUGH THE PLEURA
90
GRASP THE PERICARDIUM OVERLYING THE APEX OF THE HEART WITH THE PERICARDIAL ENTRY INSTRUMENT
91
CREATE AN OPENING THROUGH THE PERICARDIUM
93
INSERT THE ENDOSCOPIC CANNULA THROUGH THE OPENING TO ACCESS THE HEART
95

Figure 3b